Complete Summary

GUIDELINE TITLE

The care of women requesting induced abortion.

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). The care of women requesting induced abortion. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Sep. 104 p. (Evidence-based Clinical Guideline; no. 7). [361 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Royal College of Obstetricians & Gynaecologists. The care of women requesting induced abortion. London: RCOG Press; 2000. 70 p. (Evidence-based clinical guidelines; no. 7).

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- On April 10, 2006 the U.S. Food and Drug Administration (FDA) released an update to the March 17, 2006 notice (see below) regarding mifepristone (Mifeprex) and misoprostol. See the FDA Web site for more information.
- On March 17, 2006, the U.S. Food and Drug Administration (FDA) issued a public health advisory to notify healthcare professionals of two additional deaths following medical abortion with mifepristone (Mifeprex) (see below for earlier FDA alerts). The FDA received verbal notification of the deaths in the United States from the manufacturer, Danco Laboratories. At this time FDA is investigating all circumstances associated with these cases and is not able to confirm the causes of death. However, all providers of medical abortion and their patients need to be aware of the specific circumstances and directions for use of this drug and all risks including sepsis when considering treatment. In particular, physicians and their patients should fully discuss early potential signs and symptoms that may warrant immediate medical evaluation. See the FDA Web site for more information.
- On November 4, 2005 the U.S. Food and Drug Administration (FDA) released an update to the July 20, 2005 notice (see below) regarding mifepristone (Mifeprex) and misoprostol. See the FDA Web site for more information.

On July 20, 2005, Danco Laboratories and the FDA revised the BOXED WARNING and WARNINGS sections of the Prescribing Information, the Medication Guide and Patient Agreement to inform healthcare professionals of four cases of septic deaths in the United States, all reported from California, from September 2003 to June 2005 in women following medical abortion with mifepristone (Mifeprex) and misoprostol. The bacteria causing sepsis has been identified in two of the cases as Clostridium sordellii. The two confirmed cases of Clostridium sordellii did not have the usual signs and symptoms of an infection. All providers of medical abortion and their patients need to be aware of the risks of sepsis. See the FDA Web site for more information.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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SCOPE

DISEASE/CONDITION(S)

Unwanted pregnancy

GUIDELINE CATEGORY

Evaluation Management Risk Assessment Treatment

CLINICAL SPECIALTY

Family Practice Internal Medicine Nursing Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses Allied Health Personnel Hospitals Nurses Physician Assistants Physicians Public Health Departments

GUI DELI NE OBJECTI VE(S)

- To ensure that all women considering induced abortion have access to a service of uniformly high quality
- To assist clinicians and patients in making decisions about appropriate treatment

TARGET POPULATION

Women seeking abortion because the pregnancy threatens the mental or physical health of the woman or her children

This guideline does not address women seeking abortion because of the existence of a fetal abnormality.

INTERVENTIONS AND PRACTICES CONSIDERED

Evaluation/Pre-abortion Management

- 1. Patient counseling and provision of information
- 2. Prompt referral and assessment appointment within 5 days of referral
- 3. Measurement of haemoglobin, blood group determination (ABO, Rhesus [Rh]); screening for red cell antibodies (Immunoglobulin G), hepatitis B and C if indicated, and human immunodeficiency virus (HIV); testing for hemoglobinopathies
- 4. Cervical cytology history; cervical smear if not previously done at recommended interval
- 5. Ultrasound scanning
- 6. Minimizing the risk of post abortion infective morbidity (antibiotic prophylaxis or screening for lower genital tract organisms with treatment of positive cases)

Abortion Procedures

Surgical Abortion

- 1. Early surgical abortion (below 7 weeks gestation)
 - Early surgical abortion using a rigorous protocol (which includes magnification of aspirated material and indications for serum human chorionic gonadotrophin [hCG] follow-up)
- 2. Surgical abortion 7-15 weeks gestation
 - Conventional suction termination (electric or manual aspiration)
- 3. Mid-trimester surgical abortion (above 15 weeks gestation)
 - Dilatation and evacuation (D&E), preceded by cervical preparation using misoprostol (vaginal), or gemeprost (vaginal), or mifepristone (oral)

Anaesthesia and Analgesia

- 1. Anaesthesia for surgical abortion (local or general anaesthesia and conscious sedation)
- 2. Analgesia

Medical Abortion

- 1. Early medical abortion (gestations up to 9 weeks)
 - Medical abortion using a single oral dose of the anti-progesterone mifepristone followed by a single dose (vaginal or oral) of prostaglandin
- 2. Medical abortion in the late first trimester (9-13 weeks)
 - Medical abortion using a single oral dose of the anti-progesterone mifepristone followed by multiple doses (vaginal or oral) of prostaglandin
- 3. Mid-trimester medical abortion (13-24 weeks)
 - Medical abortion using a single oral dose of the anti-progesterone mifepristone followed by multiple doses (vaginal or oral) of prostaglandin

Aftercare and Follow-up

- 1. Rhesus prophylaxis (Anti-D IgG immunoprophylaxis for non-sensitized RhD negative women)
- 2. Provision of post-abortion information and follow-up appointment
- 3. Referral for further counselling (if necessary)
- 4. Discussion and offering of contraception

MAJOR OUTCOMES CONSIDERED

- Relative risk of complications from the abortion (e.g., haemorrhage [>500ml], cervical laceration, uterine perforation, retained products, infection, and maternal death)
- Failure rates/success rates of abortion procedures
- Complete abortion rate
- Secondary infertility rates
- Efficacy of medical abortion regimens
- Induction-abortion time intervals of medical abortions
- Cost
- Future reproductive outcomes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Search Strategy

In developing the earlier version of this guideline in 2000, searches were carried out for each topic of interest. The electronic database, MEDLINE (Ovid version), was searched for the period January 1966 to 1999, including foreign language publications. The searches were performed using relevant Medical Subject Heading (MeSH) terms and text words. In addition, the electronic database EMBASE was searched between 1974 to 1999, to identify publications, usually European, not indexed on MEDLINE. The Cochrane Library, up to Issue 2 (1999), was searched to identify systematic reviews, meta-analyses, and controlled clinical trials. Reference lists of non-systematic review articles and studies obtained from the initial search were trawled and journals in the Royal College of Obstetricians & Gynaecologists (RCOG) library were hand-searched to identify articles not yet indexed. There was no systematic attempt to search the "grey literature" (conferences, abstracts, theses, and unpublished trials).

In developing the updated edition, similar literature searches were carried out covering the period 1999 to September 2003. Details of all literature searches are available on application to the Faculty of Family Planning and Reproductive Health Care (FFPRHC) Clinical Effectiveness Unit.

The 2000 guideline included a short section on managing the complications of abortion. The Guideline Update Group considered that this topic had been addressed somewhat superficially. It lay outwith the main scope of the guideline and would be better omitted.

Sifting and Reviewing the Literature

For both the original and updating literature searches, a preliminary scrutiny of titles and abstracts was undertaken and full papers were obtained if relevant to the topic. Articles not relevant to the subject in question were rejected, as were articles where relevant outcomes were not reported. For all the subject areas, published systematic reviews or meta-analyses were used if available. If these did not exist, randomised controlled trials were sought. For subject areas where a body of systematic review/randomised trial evidence was available, studies of less robust designs were not systematically sought. Where there were no relevant published randomised controlled trials, other appropriate experimental or observational studies were sought.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

The definitions of the types of evidence used in this guideline originate from the United States Agency for Healthcare Research and Quality (formerly the Agency for Health Care Policy and Research).

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised trials

Ib: Evidence obtained from at least one randomised controlled trial

II a: Evidence obtained from at least one well-designed controlled study, without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasiexperimental study

III: Evidence obtained from well-designed non-experimental descriptive studies, correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVI DENCE

Review of Published Meta-Analyses Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Identified articles were assessed methodologically, and the best available evidence was used to form and support the recommendations. If a good systematic review, meta-analysis, or randomised controlled trial existed in relation to a topic, studies of a weaker design were ignored. The evidence was synthesised using qualitative methods. These involved summarising the content of identified papers in the form of evidence tables and agreeing to brief statements that accurately reflect the relevant evidence. Quantitative techniques (meta-analysis) were not performed by the guideline development team because of time constraints and the difficulty of combining studies of various designs.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Recommendations were based on, and explicitly linked to, the evidence that supports them. Recommendations were derived from available research evidence using consensus methods. Where there were areas without available research evidence, consensus was again used.

As part of the consensus process, members of the Guideline Development Group were circulated with questionnaires on which draft recommendations were listed. For each recommendation, members were asked to indicate if they thought that the recommendation should be included as it stood, included with modifications, or excluded. This questionnaire approach ensured that all group members, not

just the more vocal, had an equal opportunity to express their views on recommendations. Examination of the questionnaire responses enabled the more contentious recommendations to be identified for more detailed discussion at subsequent group meetings. The Update Group used an informal consensus process to agree modified recommendations.

The recommendations were then graded according to the level of evidence upon which they were based. The grading scheme used was formulated by the Clinical Outcomes Group and recommended by the National Health Service (NHS) Executive.

It is accepted that, in this grading system, the evidence itself is not graded according to quality, although it is discussed narratively in the text supporting each recommendation. It is also accepted that randomised controlled trials may not always be the most appropriate study design (for example, to investigate diagnostic tests). Similarly, there may be clinical questions that cannot easily be answered by experiment but nevertheless represent good practice. Such recommendations will automatically be graded C or good practice point.

The validity of some grade C and good practice point recommendations may be questionable, as they are not based upon incontrovertible evidence. However, the views of the 2000 Guideline and Update Groups combined with comments from extensive peer review, as detailed below, suggest that the recommendations with this grading are acceptable to a wide body of expert opinion.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of the recommendation (evidence levels IIa, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

COST ANALYSIS

Details of the cost effectiveness of practices discussed in the guideline are presented in the original guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Successive drafts of the original guideline were written and discussed by the Guideline Development Group. At the fourth draft stage, a formal peer review process was undertaken. Each member of the group suggested names of individuals or organisations from the area of practice that they represented. The draft guideline was submitted to these individuals or organisations with a request for appraisal and comment. The comments made by the peer reviewers were taken into consideration by the Guideline Update Group before the final guideline was generated. Under the independent guideline appraisal system approved by the National Health Service Executive, the guideline was sent to a further group of reviewers who particularly concentrated on the methodology used in its development.

For the updated guideline, the second draft of the guideline was circulated for peer review to relevant individuals chosen by the Department of Health and the Royal College of Obstetricians & Gynaecologists (RCOG). The draft was also posted on the RCOG Web site and comments invited from any Member or Fellow. Comments received were reviewed by the development team and changes were made to the document where necessary. A final draft was then approved by the RCOG Guidelines and Audit Committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

In addition to these evidence-based recommendations, the guideline development group also identifies points of best clinical practice in the original guideline document.

Levels of evidence (Ia-IV) and grading of recommendations (A–C) are defined at the end of the Major Recommendations field.

Organisation of Services

B - The earlier in pregnancy an abortion is performed, the lower the risk of complications. Services should therefore offer arrangements that minimise delay (for example, a telephone referral system and a formal care pathway with arrangements for access from a wide range of referral sources, not just general practitioners).

Service arrangements should be such that:

- Ideally, all women requesting abortion are offered an assessment appointment within 5 days of referral.
- As a minimum standard, all women requesting abortion are offered an assessment appointment within 2 weeks of referral.
- Ideally, all women can undergo the abortion within 7 days of the decision to proceed being agreed.
- As a minimum standard, all women can undergo the abortion within 2 weeks of the decision to proceed being agreed.
- C As a minimum standard, no woman need wait longer than 3 weeks from her initial referral to the time of her abortion.

- Women should be seen as soon as possible if they require termination for urgent medical reasons.
- C An adequate number of staffed inpatient beds must be available for those women who are unsuitable for day case care. In a typical abortion service, up to 5% of women will require inpatient care.

Information for Women

- B Verbal advice should be supported by accurate, impartial printed information that the woman considering abortion can understand and may take away to consider further before the procedure.
- B The risk of haemorrhage at the time of abortion is low. It complicates around 1 in 1,000 abortions overall. The risk is lower for early abortions (0.88 in 1,000 at less than 13 weeks; 4.0 in 1,000 at more than 20 weeks).
- B The risk of uterine perforation at the time of surgical abortion is moderate. The incidence is of the order of 1–4 in 1,000. The risk is lower for abortions performed early in pregnancy and those performed by experienced clinicians.
- B Uterine rupture has been reported in association with mid-trimester medical abortion. However, the risk is very low, at well under 1 in 1,000.
- B Cervical trauma: The risk of damage to the external cervical os at the time of surgical abortion is moderate (no greater than 1 in 100). The risk is lower when abortion is performed early in pregnancy and when it is performed by an experienced clinician.
- B Failed abortion and continuing pregnancy: All methods of first-trimester abortion carry a small risk of failure to terminate the pregnancy, thus necessitating a further procedure. The risk for surgical abortion is around 2.3 in 1,000 and for medical abortion between 1 and 14 in 1,000 (depending on the regimen used and the experience of the centre).
- B Post-abortion infection: Genital tract infection, including pelvic inflammatory disease of varying degrees of severity, occurs in up to 10% of cases. The risk is reduced when prophylactic antibiotics are given or when lower genital tract infection has been excluded by bacteriological screening.
- B Breast cancer: Induced abortion is not associated with an increase in breast cancer risk.
- B Future reproductive outcome: There are no proven associations between induced abortion and subsequent ectopic pregnancy, placenta praevia, or infertility. Abortion may be associated with a small increase in the risk of subsequent miscarriage or preterm delivery.
- B Psychological sequelae: Some studies suggest that rates of psychiatric illness or self-harm are higher among women who have had an abortion compared with women who give birth and to nonpregnant women of similar age. It must be

borne in mind that these findings do not imply a causal association and may reflect continuation of pre-existing conditions.

Pre-abortion Management

The Abortion Decision

C - Clinicians caring for women requesting abortion should try to identify those who require more support in decision making than can be provided in the routine clinic setting (such as those with a psychiatric history, poor social support, or evidence of coercion). Care pathways for additional support, including access to social services, should be available.

Blood Tests

- C Pre-abortion assessment should include:
- Measurement of haemoglobin concentration
- Determination of ABO and rhesus blood groups with screening for red cell antibodies
- Testing for other conditions such as haemoglobinopathies, human immunodeficiency virus (HIV), and hepatitis B and C if indicated in the light of clinical features, individual risk factors, or local prevalence
- B It is not cost effective routinely to crossmatch women undergoing induced abortion.

Ultrasound Scanning

- B All services must have access to scanning, as it can be a necessary part of pre-abortion assessment, particularly where gestation is in doubt or where extrauterine pregnancy is suspected. However, ultrasound scanning is not considered to be an essential prerequisite of abortion in all cases.
- C When ultrasound scanning is undertaken, it should be in a setting and manner sensitive to the woman's situation. It is inappropriate for pre-abortion scanning to be undertaken in an antenatal department alongside women with wanted pregnancies.

Prevention of Infective Complications

- A Abortion care should encompass a strategy for minimising the risk of post-abortion infective morbidity. As a minimum, services should offer antibiotic prophylaxis.
- B Ideally, services should offer testing for lower genital tract organisms with treatment of positive cases.
- C The following regimens are suitable for periabortion prophylaxis:
- Metronidazole 1 gram (g) rectally at the time of abortion

plus

 Doxycycline 100 milligrams (mg) orally twice daily for 7 days, commencing on the day of abortion

OR

- Metronidazole 1 g rectally at the time of abortion plus
- Azithromycin 1 g orally on the day of abortion.

Abortion Procedures

B - Ideally, abortion services should be able to offer a choice of recommended methods for each gestation band.

Surgical Methods

- B Conventional suction termination should be avoided at gestations below 7 weeks.
- B Early surgical abortion using a rigorous protocol (which includes magnification of aspirated material and indications for serum beta-human chorionic gonadotrophin [hCG] follow-up) may be used at gestations below 7 weeks, although data suggest that the failure rate is higher than for medical abortion.
- B Conventional suction termination is an appropriate method at gestations of 7-15 weeks, although, in some settings, the skills and experience of practitioners may make medical abortion more appropriate at gestations above 12 weeks.
- B Suction termination is safer under local anaesthesia than under general anaesthesia. Consideration should be given to making this option available, particularly for low gestation procedures.
- C If conscious sedation is used in place of general anaesthesia to reduce the pain and anxiety associated with surgical abortion, it should be undertaken only by trained practitioners and in line with Department of Health guidance.
- A For first-trimester suction termination, either electric or manual aspiration devices may be used, as both are effective and acceptable to women and clinicians. Operating times are shorter with electric aspiration.
- A For gestations above 15 weeks, surgical abortion by dilatation and evacuation (D&E), preceded by cervical preparation, is safe and effective when undertaken by specialist practitioners with access to the necessary instruments and who have a sufficiently large caseload to maintain their skills.

- B Cervical preparation is beneficial prior to surgical abortion and should be routine if the woman is aged under 18 years of age or at a gestation of more than 10 weeks.
- C Abortion regimens containing misoprostol are not licensed within manufacturers' summaries of product characteristics. European Community regulations permit doctors to prescribe unlicensed regimens and permit pharmacists to dispense and nurses to administer medicines prescribed outside of a product license. Women should be informed if a prescribed treatment is unlicensed.
- B Based on available evidence, the following regimen appears to be optimal for cervical preparation prior to first- or second-trimester surgical abortion. This advice is based on considerations of efficacy, adverse-effect profile, and cost:
 - * Misoprostol 400 micrograms (2 x 200-microgram tablets) administered vaginally, either by the woman or a clinician, 3 hours prior to surgery

The following regimens are licensed within manufacturers' summaries of product characteristics and are also appropriate for cervical preparation prior to first- or second trimester surgical abortion:

- Gemeprost 1 mg vaginally, 3 hours prior to surgery
- Mifepristone 600 mg orally 36-48 hours prior to surgery.
- * This regimen is unlicensed.

Medical Methods

- B Medical abortion using mifepristone plus prostaglandin is the most effective method of abortion at gestations of less than 7 weeks.
- A Medical abortion using mifepristone plus prostaglandin continues to be an appropriate method for women in the 7-9 week gestation band.
- A * For early medical abortion a dose of 200 mg of mifepristone in combination with a prostaglandin is appropriate.
- A * Misoprostol (a prostaglandin E_1 analogue) is a cost-effective alternative for all abortion procedures for which the E_1 analogue gemeprost is conventionally used (that is, early medical abortion, cervical priming, mid-trimester medical abortion).
- B Based on available evidence, the following regimen appears to be optimal for early medical abortion up to 9 weeks (63 days) of gestation. This advice is based on considerations of efficacy, adverse-effect profile, and cost:
 - * Mifepristone 200 mg orally followed 1-3 days later by misoprostol 800 micrograms vaginally. The misoprostol may be administered by a

clinician or self-administered by the woman. For women at 49-63 days of gestation, if abortion has not occurred 4 hours after administration of misoprostol, a second dose of misoprostol 400 micrograms may be administered vaginally or orally (depending upon preference and amount of bleeding).

The following regimen is licensed within manufacturer's summary of product characteristics and is also appropriate for early medical abortion up to 9 weeks (63 days) of gestation:

- * Mifepristone 600 mg orally followed 36-48 hours later by gemeprost 1 mg vaginally
- A Medical abortion using the following regimen is a safe, effective, and acceptable alternative to surgical abortion for women between 9 and 13 weeks of gestation:
 - * Mifepristone 200mg orally followed 36-48 hours later by misoprostol 800 micrograms vaginally. A maximum of four further doses of misoprostol 400 micrograms may be administered at 3-hourly intervals, vaginally or orally (depending on the amount of bleeding).
- B For mid-trimester abortion (13-24 weeks of gestation) medical abortion with mifepristone followed by prostaglandin is an appropriate method and has been shown to be safe and effective.
- A For mid-trimester medical abortion, a dose of *200 mg of mifepristone is adequate.
- B Surgical evacuation of the uterus is not required routinely following midtrimester medical abortion. It should only be undertaken if there is clinical evidence that the abortion is incomplete.
- A Based on available evidence, the following regimen appears to be optimal for midtrimester medical abortion. This advice is based on considerations of efficacy, adverse effect profile, and cost:
 - * Mifepristone 200 mg orally, followed 36-48 hours later by misoprostol 800 micrograms vaginally, then misoprostol 400 micrograms orally, 3-hourly, to a maximum of four oral doses

The following regimen is licensed within manufacturer's summary of product characteristics and is also appropriate for mid-trimester medical abortion.

- * Mifepristone 600 mg orally, followed 36–48 hours later by gemeprost 1 mg vaginally every 3 hours, to a maximum of five pessaries.
- * This regimen is unlicensed.

General

B - Some women will require analgesia after surgical abortion or during and after medical abortion. Requirements for analgesia vary and there is no benefit in

routine administration of prophylactic analgesics. Services should make available a range of oral and parenteral analgesics in order to meet women's needs.

B - Routine histopathological examination of tissue obtained at abortion procedures is unnecessary.

Aftercare

Rhesus Prophylaxis

B - Anti-D immunoglobulin G (250 international units [iu] before 20 weeks of gestation and 500 iu thereafter) should be given, by injection into the deltoid muscle, to all nonsensitised RhD negative women within 72 hours following abortion, whether by surgical or medical methods.

Post-Abortion Information and Follow-up

- C Each woman should be offered, or advised to obtain, a follow-up appointment (either within the abortion service or with the referring clinician) within 2 weeks of the abortion.
- C Referral for further counselling should be available for the small minority of women who experience long-term post-abortion distress. Risk factors are ambivalence before the abortion, lack of a supportive partner, a psychiatric history, or membership of a cultural group that considers abortion to be wrong.

Contraception Following Abortion

- B Before she is discharged following abortion, future contraception should have been discussed with each woman and contraceptive supplies should have been offered if required. The chosen method of contraception should be initiated immediately following abortion.
- B Intrauterine contraception can be inserted immediately following a first- or second trimester termination of pregnancy.
- B Sterilisation can be safely performed at the time of induced abortion. However, combined procedures are associated with higher rates of failure and of regret on the part of the woman.

Definitions:

Levels of Evidence

Ia: Evidence obtained from meta-analysis of randomised trials

Ib: Evidence obtained from at least one randomised controlled trial

II a: Evidence obtained from at least one well-designed controlled study, without randomisation

IIb: Evidence obtained from at least one other type of well-designed quasiexperimental study

III: Evidence obtained from well-designed non-experimental descriptive studies,

correlation studies, and case studies

IV: Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

Grading of Recommendations:

Grade A - Requires at least one randomised controlled trial as part of a body of literature of overall good quality and consistency addressing the specific recommendation (evidence levels Ia, Ib)

Grade B - Requires the availability of well-conducted clinical studies but no randomised clinical trials on the topic of the recommendation (evidence levels IIa, III)

Grade C - Requires evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates an absence of directly applicable clinical studies of good quality (evidence level IV)

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

It is anticipated that there will be health benefits for women seeking induced abortion in the form of consistent, high quality service, and prompt, effective treatment.

Additional benefits include:

- Reduced risk of complications
- Reduced costs
- Increased success rate

POTENTIAL HARMS

Complications of Abortion

• Immediate complications include haemorrhage, uterine perforation, cervical lacerations, and anaesthetic complications. Women must be informed that,

- should one of these complications occur, further treatment in the form of blood transfusion, laparoscopy, or laparotomy may be required.
- Complications in the early weeks following abortion, include incomplete abortion requiring re-evacuation, continuing pregnancy requiring a further abortion procedure, pelvic infection, and short-term emotional distress.
- Long-term effects which may, rarely, be associated with abortion, include miscarriage or preterm birth and psychological problems.
- Side effects of agents used for medical abortion

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The guideline was developed in relation to abortion legislation and available resources in England, Wales, and Scotland. The different issues surrounding induced abortion in countries with different legislation and with different levels of resources and facilities are not considered.
- Product liability: the Royal College of Obstetricians & Gynaecologists (RCOG)
 can give no guarantee for information about drug dosage and application
 thereof contained in this guideline. In every individual case the respective
 user must check its accuracy by consulting other pharmaceutical literature.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Local Protocol Development

It is anticipated that this national guideline will be used as the basis for the development of local protocols or guidelines which will take into account local service provision and the needs and preferences of the local population. Such local adaptation should take place in a similar multidisciplinary group in consultation with all parties affected by the guidelines. It is essential that commissioners of healthcare, as well as general practitioners, specialists, and service users, take part in such a process.

Standards for Audit

The Guideline Development Group and Update Group are committed to the concept of integrated clinical effectiveness activities. It is fundamental to this concept that guideline development is complemented by related audit activity. Abortion services at local level are encouraged to conduct regular audit of the care they provide. The recommendations within this guideline can serve as criteria for audit. Suggestions for audit of abortion services were provided within the Royal College of Obstetricians & Gynaecologists (RCOG) document, entitled "Effective Procedures in Gynaecology Suitable for Audit". Some illustrative examples of these audit suggestions, with modifications in the light of this new guideline, are summarised in the original guideline document.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators Patient Resources Quick Reference Guides/Physician Guides

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Staying Healthy

IOM DOMAIN

Effectiveness Patient-centeredness Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Royal College of Obstetricians and Gynaecologists (RCOG). The care of women requesting induced abortion. London (UK): Royal College of Obstetricians and Gynaecologists (RCOG); 2004 Sep. 104 p. (Evidence-based Clinical Guideline; no. 7). [361 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 (revised 2004 Sep)

GUIDELINE DEVELOPER(S)

Royal College of Obstetricians and Gynaecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

This guideline was supported by funding awarded by the Department of Health (DH).

GUI DELI NE COMMITTEE

RCOG Guideline Update Group

RCOG Guidelines and Audit Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Royal College of Obstetricians and Gynaecologists (RCOG) Guideline Update Group Members: Dr Gillian Penney (Chair), Scottish Programme for Clinical Effectiveness in Reproductive Health, RCOG nominee; Dr Susan Brechin, FFPRHC Clinical Effectiveness Unit; Dr Ken Bidgood, RCOG nominee; Ms Ann Furedi, bpas, charitable sector representative; Mrs Susie Marwood, RCOG Consumers' Forum representative; Dr Kate Guthrie, FFPRHC nominee; Dr Sharon Hopkins, Faculty of Public Health Medicine nominee; Dr Hilary McDermott, Royal College of General Practitioners nominee; Ms Hazel McBain, Nurse Counsellor; Mr Sam Mirando, FFPRHC nominee; Mr Anthony Parsons, RCOG nominee; Dr Connie Smith, FFPRHC nominee; Dr Sam Rowlands, bpas, charitable sector representative; Dr Helen Ribbans, FFPRHC nominee; Mr Michael Bowen, Department of Health observer; Miss Gillian Stephen, Research Assistant

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Guideline Development Group made formal declarations of interest at the outset, which were recorded. This record is kept on file at the Royal College of Obstetricians and Gynaecologists (RCOG). The College was of the opinion that the interests declared did not conflict with the guideline development process.

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Royal College of Obstetricians & Gynaecologists. The care of women requesting induced abortion. London: RCOG Press; 2000. 70 p. (Evidence-based clinical guidelines; no. 7).

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the <u>Royal</u> College of Obstetricians and Gynaecologists Web site.

Print copies: Available from the Royal College of Obstetricians and Gynaecologists (RCOG) Bookshop, 27 Sussex Place, Regent's Park, London NW1 4RG; Telephone: +44 020 7772 6276; Fax, +44 020 7772 5991; e-mail: bookshop@rcog.org.uk. A listing and order form are available from the RCOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 The care of women requesting induced abortion. Summary of recommendations. London: RCOG Press; 2004. 15 p.

Electronic copies: Available in Portable Document Format (PDF) from the <u>Royal</u> <u>College of Obstetricians and Gynaecologists Web site</u>.

Additionally, audit criteria are summarized in Chapter 9 of the <u>original guideline</u> document.

PATIENT RESOURCES

The following is available:

 About abortion care: what you need to know. Royal College of Obstetricians and Gynaecologists (RCOG), 2004 Sep. 12 p.

Electronic copies: Available from the <u>Royal College of Obstetricians and</u> Gynaecologists Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

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